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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/995,010 | 11/27/2001 | Stanislaw R. Burzynski | BURG:04910379.0049.NPUS00 | 9045 |

7590

10/08/2002

HOWREY SIMON ARNOLD & WHITE
750 Bering Drive
Houston, TX 77057-2198

EXAMINER

JONES, DWAYNE C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,010

Applicant(s)

BURZYNSKI, STANISLAW R.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Claims 1-31 are pending.
2. Claims 1-31 are rejected.

Information Disclosure Statement

3. The information disclosure statement filed on March 5, 2002 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al. of U.S. Patent No. 5,719,134. Schmidl et al. teach of a dietary

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composition useful for providing nutrition to individuals with diseases, especially individuals who are unable to consume food orally and must be fed enterally, (see column 1). Schmidl et al. teach a preferred composition which contains L-arginine, L-alanine, glycine, L-serine, taurine, L-threonine, L-valine, and riboflavin, (see column 4, line 21 to column 5, line 12). The instant claimed pharmaceutical claims are in fact pharmaceutical claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In addition, Schmidl et al. do teach one having ordinary skill in the art that these claims are pharmaceutical claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease, (see column 1, lines 28-30 and lines 37-67). Accordingly, it would have been obvious to the skilled artisan to utilize this nutritional composition of Schmidl et al. to treat a variety individuals, who suffer from malnutrition due to a disease or condition which causes or is associated with the malnutrition.

7. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. of U.S. Patent No. 5,550,146. Acosta et al. disclose of a nutritional composition, which contains vitamins and amino acids, for the treatment of various metabolic diseases, (see abstract and columns 1 and 2). In fact, Acosta et al. specifically recite the following constituents of taurine and riboflavin, (as cited from Table 1, column 17) and L-alanine, L-arginine, glycine, L-serine, L-threonine and L-

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valine, (as listed in Table 3, column 21). The instant claimed pharmaceutical claims are in fact pharmaceutical claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S 327, 65 USPQ 297 (1945). Even though the prior art reference of Acosta et al. is directed to treating inherited metabolic disorders, the compositions of Acosta et al. do teach of pharmaceutical compositions which render the instant invention obvious. In addition, because Acosta et al. do teach that the administration of these nutritional compositions are used to treat metabolic disorders, the skilled artisan would have been motivated to utilize the compositions of Acosta et al. to treat other diseases, ailments or conditions where metabolic disorders are treatable with the administration of dietary, nutritional compositions. Accordingly, it would have been obvious to one having ordinary skill in the art to utilize the nutritional compositions of Acosta et al. to treat metabolic disorders caused by a variety of diseases or conditions, such as cancer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
October 5, 2002